

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Impact of developmental care on length of stay in infant undergoing mechanical ventilation

#### Protocol summary

##### Summary

This is a quasi-experimental study was done to investigate the impact of developmental care on length of mechanical ventilation on 60 inpatient neonates who undergo mechanical ventilation at 4 hospital affiliated to Shahid Beheshti University of Medical Sciences. A convenience sample was selected from 4 hospital in Tehran, Iran that nonrandomly assigned to interventional from Mahdiah Hospital (n=30) and control group (n=30) from other 3 hospital (Mofid Children's Hospital, Imam Hossein Hospital and Shohada Tajrish Hospital). Inclusion criteria: gestational age less than 33 weeks with birth weight equal or less than 2500 g; neonates suffered from respiratory distress syndrome; mechanical ventilation > 24 hours of first 48 hours of life and exclusion criteria: treatment with surfactant, congenital anomalies; asphyxia; respiratory disorders; cyanotic heart disease; mouth and facial abnormalities; maternal use of opium drugs during pregnancy; neonatal death; intraventricular hemorrhage (grade 3 or 4) alongside hydrocephalus; sepsis, necrotizing enterocolitis; growth disorders; bronchopulmonary dysplasia; patent ductus arteriosus requiring treatment; pneumonia caused by mechanical ventilation. Data collection included demographic information that completed under supervision of researchers in the hospitals for intervention groups. Developmental care intervention consist of: change the position every 2-3 hours, hand near face, nesting, Right side or prone position to improve gastric emptying and reduce the effects of gastroesophageal reflux, non-nutritive sucking before invasive intervention and gavage, Using gentle and quiet handling techniques, trunk flexion, shoulder and hip flexion and adduction, prevent suddenly change position and Keep hands of care keeper over the baby's head before beginning any care for providing the infant's sense of care. Care in the intervention group was maintained until the end of the need for mechanical ventilation. Daily nursing care for infants in the control group was conducted.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2015070123003N1**

Registration date: **2015-08-09, 1394/05/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-08-09, 1394/05/18

##### Registrant information

###### Name

Sima Sabaghi Faradonbeh

###### Name of organization / entity

International Branch of Beheshti University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3422 6542

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Investigator

##### Expected recruitment start date

2015-02-04, 1393/11/15

##### Expected recruitment end date

2015-06-05, 1394/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**  
Impact of developmental care on length of stay in infant undergoing mechanical ventilation

**Public title**  
Developmental care

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
Inclusion criteria: gestational age less than 33 weeks with birth; weight equal or less than 2500 g; neonates suffered from respiratory distress syndrome; mechanical ventilation > 24 hours of first 48 hours of life. Exclusion criteria: treatment with surfactant; congenital anomalies; asphyxia; respiratory disorders; cyanotic heart disease; mouth and facial abnormalities; maternal use of opium drugs during pregnancy; neonatal death; intraventricular hemorrhage ( grade 3 or 4) alongside hydrocephalus; sepsis; necrotizing enterocolitis ; growth disorders; bronchopulmonary dysplasia; patent ductus arteriosus requiring treatment; pneumonia caused by mechanical ventilation.

**Age**  
To 28 days old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: 60

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**  
**Name of ethics committee**  
The ethics committee of International Branch of Behesti University of Medical Sciences and Health S  
**Street address**  
No.19, Next to Hemat bridge, Street SHahid Abbaspoor, Vali asr(AJ), Tehran  
**City**

Tehran  
**Postal code**  
14155-3693  
**Approval date**  
2015-02-04, 1393/11/15  
**Ethics committee reference number**  
1000/912

## Health conditions studied

### 1

**Description of health condition studied**  
respiratory distress syndrome  
**ICD-10 code**  
p 22.0  
**ICD-10 code description**  
Hyaline membrane disease

## Primary outcomes

### 1

**Description**  
Developmental care  
**Timepoint**  
after intervention  
**Method of measurement**  
Data collection included three part demographic questioner. First part, demographic information including weight, sex, age, type of birth, apgar score at the first minute, apgar score at 5 minute that completed under supervision of researchers at the hospitals for intervention groups. Secondary part including developmental care interventions consist of: change the position every 2-3 hours, hand near face, nesting, Right side or prone position to improve gastric emptying and reduce the effects of gastroesophageal reflux, non-nutritive sucking before invasive intervention and gavage, Using gentle and quiet handling techniques, trunk flexion, shoulder and hip flexion and adduction, prevent suddenly change position and Keep hands of care keeper over the baby's head before beginning any care for providing the infant's sense of care and third part including the onset and end time that need for mechanical ventilation.

## Secondary outcomes

### 1

**Description**  
Duration of mechanical ventilation  
**Timepoint**  
Since the beginning of mechanical ventilation until maintained until the end of the need for mechanical ventilation.  
**Method of measurement**  
Number of days

## Intervention groups

### 1

#### Description

Researcher in NICU Mahdieh Hospital will present and in relation with the developmental intervention, required explanations will give to nurses. In researcher initially will introduce herself and objectives to the parents of neonates who had inclusion criteria for the study and will sign an informed consent by parents. Then, the first part of a demographic questionnaire will complete by the researcher and the date of onset of mechanical ventilation will record. Developmental care interventions will receive by all neonates who had eligible for inclusion through a trained nurse. Care in the intervention group will maintain until the end of the need for mechanical ventilation.

#### Category

N/A

### 2

#### Description

Inpatient neonates of NICUS Mofid Children's Hospital, Imam Hossein and Shohada Tajrish, Tehran as the control group will receive daily care. Researcher in theses hospitals will attend and demographic information questionnaire will fulfill, also the onset and end time that need for mechanical ventilation for 30 cases will record.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mahdieh Hospital

##### Full name of responsible person

Seyyed Abolfazl Afje

##### Street address

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran

##### City

Tehran

### 2

#### Recruitment center

##### Name of recruitment center

Mofid Childrens Hospital

##### Full name of responsible person

Minoo Fallahi

##### Street address

Shariati Ave, Tehran, Iran

##### City

Tehran

### 3

#### Recruitment center

##### Name of recruitment center

Imam Hossein Hospital

##### Full name of responsible person

Ms. Shahrinani

##### Street address

Madani Ave, Tehran, Iran

##### City

Tehran

### 4

#### Recruitment center

##### Name of recruitment center

Shohada Tajrish Hospital

##### Full name of responsible person

Mahta Fateme Basir

##### Street address

Tajrish Sq., Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

-

##### Full name of responsible person

-

##### Street address

-

##### City

-

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

-

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

International Branch of Beheshti University of Medical Science and Health Services

##### Full name of responsible person

Sima Sabaghi Faradonbeh

**Position**

Master student

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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of Nursing and Midwifery

**Full name of responsible person**

Manigheh Nourian

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Science Committee

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## Person responsible for updating data

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International Branch of Beheshti University of Medical  
Science and Health Services

**Full name of responsible person**

Sima Sabaghi Faradonbeh

**Position**

Master student

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*